**NOT FOR PUBLICATION**

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY
CAMDEN VICINAGE

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| THERAVANCE BIOPHARMA R&D IP, LLC, *et al.*,<br><br>Plaintiffs,<br><br>v.<br><br>EUGIA PHARMA SPECIALTIES LTD., *et al.*,<br><br>Defendants. | HONORABLE KAREN M. WILLIAMS<br><br>Civil Action<br>No. 23-926 (KMW-AMD)<br><br>**OPINION** |

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**WILLIAMS, District Judge:**

## I. INTRODUCTION

This matter comes before this Court on Plaintiff Theravance Biopharma US, Inc., Theravance Biopharma Ireland Limited, Mylan Ireland Limited, and Mylan Specialty LLC's, (collectively, "Plaintiffs"), Motion to Seal, (ECF No. 293), Eugia US LLC, Aurobindo Pharma USA, Inc., and Aurobindo Pharma Limited's, ("Eugia Defendants"), Motion to Seal, (ECF No. 347), Defendant Cipla Limited, Cipla USA, Inc, ("Cipla Defendants"), and Mankind Pharma Ltd, and Lifestar Pharma LLC's, ("Mankind Defendants"), joint Motion to Seal, (ECF No. 359), and Cipla Defendants' individual Motion to Seal, (ECF No. 381). All motions are unopposed.

For the reasons that follow, the Court **GRANTS** the pending Motions to Seal, (ECF Nos. 293, 347, 359, 381).

## II. BACKGROUND

The Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301-99 governs the process by which a company seeking to market a new brand-name drug brings the product to market after the Food and Drug Administration ("FDA") is satisfied that there is sufficient safety and effectiveness. *See Celgene Corp. v. Teva Pharms. USA, Inc.*, 412 F. Supp. 2d 439, 440 (D.N.J. 2006). The Hatch-Waxman Act, (codified at 21 U.S.C. § 355 and 35 U.S.C. §§ 156, 271, and 282), amended the process to enable generic manufacturers to bring generic products to the market faster by allowing them to avoid the costly process of additional testing through the Abbreviated New Drug Application ("ANDA") which allows the generic to utilize the safety and effectiveness information that the brand-name manufacturers had to submit to bring their new drug to market provided that the proposed generic drug is chemically bioequivalent. *Id.* at 440-41.

ANDAs must address the patents that are applicable to the generic drug for which approval is sought and pursuant to 21 U.S.C. 355(j)(2)(A)(vii) and certify the ANDA in one of four ways: 1) that the patent information has not been filed before (i.e. the patent is for a new product), 2) that the patent has expired, 3) that the generic will wait to launch when the applicable patent at issue expires, or 4) that the applicable patent is invalid, or will not be infringed by the manufacture, use or sale of the generic. *See* 21 U.S.C. 355(j)(2)(A)(vii)(I-IV). "Applicants use Paragraph IV Certifications to essentially challenge the validity of the brand-name drug manufacturers' patents[,]" and thus the certification is considered an "artificial" act of infringement, requiring the ANDA applicant to give notice to the brand-name manufacturer and permit the brand-name manufacturer to litigate to protect its patent rights. *Celegene Corp.*, 412 Supp. 2d at 441; *see also Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 678 (1990).

Here, Plaintiffs developed and launched YUPELRI®, (revefenacin), a prescription medication for patients with chronic obstructive pulmonary disease ("COPD"). *See* Amend. Compl. at ¶¶ 166-67. COPD is a chronic inflammatory disease of the lungs, with progressive persistent airflow obstruction, causing patients to have difficulty breathing both when inhaling and exhaling. YUPELRI® is a long-acting muscarinic antagonist, (a bronchodilator), that can be administered orally once per day via jet nebulizer, enabling COPD patients with low expiratory volume, (measured as $FEV_1$[1] of equal to or greater than 30% and less than 50% being "severe" and $FEV_1$ of less than 30% as "very severe"), and low inspiratory flow rate, (measured as suboptimal PIFR[2] of less than 60 L/min, which may prevent a patient from achieving clinical benefit of a dry powder inhaler, and a PIFR of less than 30 L/min being insufficient to use a dry power inhaler), to properly respire the medication. *Id.* at ¶¶ 167, 173-179. The following patents

[1] Forced Expiratory Volume in One Second.
[2] Peak Inspiratory Flow Rate.

are related to YUPELRI® and are listed in the FDA's "Orange Book"[3]: '451, '028, '081, '289, '531, and '948, (collectively, the "Orange Book Patents"). *Id.* at ¶¶ 136-153.

In January of 2023, each of the Eugia, Cipla, and Mankind Defendants submitted their notice to Plaintiffs pursuant to 21 U.S.C. § 355(j)(2)(B) and 21 C.F.R. § 314.95, alerting Plaintiffs that each had submitted an ANDA to the FDA pursuant to 21 U.S.C. (j)(1) and 2(A), seeking approval to engage in the commercial manufacture, use, or sale of a generic version of YUPELRI® prior to the expiration of patents '451, '028, '081, '289, '531. *Id.* at ¶¶ 180, 207, 373. Each notice letter also included Paragraph IV Certification asserting that the patents at issue were invalid, unenforceable, and/or not infringed upon by the generic product. *Id.* at ¶¶ 181, 208, 374. In July of 2023, the '948 patent related to YUPELRI® was granted and included in the Orange Book, and subsequently each of the Eugia, Cipla, and Mankind Defendants submitted their notice and Paragraph IV Certifications related to the '948 patent. *Id.* at ¶¶ 185-189, 213-216, 378-381. On December 4, 2023, Plaintiffs amended their Complaint to further assert that Defendants are infringing upon additional patents that are not listed in the Orange Book: '783, '099, '013, '209, (the "non-Orange Book patents").[4] *See* Mot. to Dismiss at 5. Since the Amended Complaint was filed, Plaintiffs have filed two other actions, which have since been consolidated.[5] *Id.* at 5.

Plaintiffs and Defendants have engaged in substantial briefing in this matter, and as a result, all of the parties have filed for Motions to Seal for various documents pursuant to New Jersey Local Civil Rule 5.3 to protect their confidential business information.

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[3] The U.S. Food and Drug Administration ("FDA") publishes the *Approved Drug Products with Therapeutic Equivalence Evaluations*, commonly known as the "Orange Book" which identifies drug products approved on the basis of safety and effectiveness, along with patent and exclusivity information. *See* "Approved Drug Products with Therapeutic Equivalence Evaluations | Orange Book," U.S. Food & Drug Administration, https://www.fda.gov/drugs/drug-approvals-and-databases/approved-drug-products-therapeutic-equivalence-evaluations-orange-book (last visited on May 27, 2025).

[4] These patents do not have any certifications against them because they are not listed in the Orange Book.

[5] The Court notes that two other actions were consolidated to the case at bar, which brings two additional patents to this matter ('898, '692). *See* Mot. to Dismiss at 7 n.6; Opp at. 5.

## III. LEGAL STANDARD

Requests to seal are governed by New Jersey Local Civil Rule 5.3, which requires that a request to seal must be presented by motion, and that the motion papers must describe "(a) the nature of the materials or proceedings at issue, (b) the legitimate private or public interests which warrant the relief sought, (c) the clearly defined and serious injury that would result if the relief sought is not granted, and (d) why a less restrictive alternative to the relief sought is not available." L. Civ. R. 5.3(c)(2).

Although there is a well-established "common law public right of access to judicial proceedings and records," *In re Cendant Corp.*, 260 F.3d 183, 192 (3d Cir. 2001), "[i]n order to overcome this presumption of a public right of access, the movant must demonstrate that 'good cause' exists for the protection of the material at issue." *Securimetrics, Inc. v. Iridian Techs., Inc.*, No. 03-4394, 2006 WL 827889, at *2 (D.N.J. Mar. 30, 2006). Good cause exists when a party makes a particularized showing that disclosure will cause a "clearly defined and serious injury to the party seeking closure." *Id.* (citing *Pansy v. Borough of Stroudsburg*, 23 F.3d 772, 786 (3d Cir. 1994)). Specifically, the movant must prove that the information is confidential in nature and that allowing the general public to access the information will cause a specific and serious injury. *See Pansy*, 23 F.3d at 786. "'Broad allegations of harm, unsubstantiated by specific examples or articulated reasoning,' do not support a good cause showing." *Id.* (citing *Cipollone v. Liggett Group, Inc.*, 785 F.2d 1108, 1121 (3d Cir. 1986)).

## IV. DISCUSSION

Plaintiffs, (ECF No. 293), Eugia Defendants, (ECF No. 347), Cipla and Mankind Defendants jointly, (ECF No. 359), and Cipla Defendants individually (ECF No. 381), seek to seal several Exhibits and redact certain portions of transcripts to preserve the confidentiality of

proprietary and non-public information related to the underlying patent dispute. Because these requests to seal involve the same kinds of nonpublic, closely guarded business information, and with all requests unopposed, the Court will address all motions below.

The Court must review the pending motions against the four factors as promulgated in L. Civ. R. 5.3(c)(2). First, all motions clearly describe the nature of the materials at issue, thus meeting the first prerequisite, noting that these documents, while necessary for the Court's review to resolve the pending motions, contain sensitive, non-public information relating to the parties' research, development, and commercialization of various products, as well as confidential communications regarding the underlying patent dispute. *See* Mot. Seal (ECF No. 293), Decl. Mary W. Bourke at ¶¶ 2, 4, 5, 7-9; Decl. Matthew V. Anderson at ¶¶ 2, 4, 5, 7-9; Mot. Seal (ECF No. 347), Decl. George J. Barry, III at ¶¶ 2, 6, 10; Mot. Seal (ECF No. 359), Decl. Loly G. Tor at ¶¶ 2, 3, 4, 6, 8; Decl. Jay P. Lesser at ¶¶ 2, 6; Mot. Seal (ECF No. 381), Decl. Loly G. Tor at ¶¶ 2-4, 6, 8.

Second, all motions assert the legitimate private and public interests which warrant the relief sought, such as to protect the confidential proprietary information or trade secrets, nonpublic regulatory and research development strategies, and confidential communications regarding potential settlement of certain claims, all serving to maintain a competitive marketplace. *See* Mot. Seal (ECF No. 293), Decl. Mary W. Bourke at ¶¶ 8-9; Decl. Matthew V. Anderson at ¶¶ 8-9; Mot. Seal (ECF No. 347), Decl. George J. Barry, III at ¶¶ 9; Mot. Seal (ECF No. 359), Decl. Loly G. Tor at ¶¶ 7-8; Decl. Jay P. Lesser at ¶¶ 6; Mot. Seal (ECF No. 381), Decl. Loly G. Tor at ¶¶ 7-8.

Third, all motions assert the clearly defined and serious injury that would result if the relief sought is not granted, such as the exposure of sensitive research and development information and trade secrets to the public, that is normally not widely available. *See* Mot. Seal (ECF No. 293),

Decl. Mary W. Bourke at ¶ 8; Decl. Matthew V. Anderson at ¶ 8; Mot. Seal (ECF No. 347), Decl. George J. Barry, III at ¶¶ 8-9; Mot. Seal (ECF No. 359), Decl. Loly G. Tor at ¶ 7; Decl. Jay P. Lesser at ¶ 7; Mot. Seal (ECF No. 381), Decl. Loly G. Tor at ¶¶ 7-8.

Fourth, the Court agrees that there is no less restrictive alternative to filing the information requested as proposed by the parties. Plaintiffs seek to apply limited redactions on Exhibits 2, 3, 10, and 11, (of ECF No. 261), limited redactions to Eugia Defendant's letter and Exhibit Z, (of ECF No. 270), and limited redactions to sections of the transcript (ECF No. 281). *See* Mot. to Seal (ECF No. 293), Decl. Mary W. Bourke at ¶ 10; Decl. Matthew V. Anderson at ¶ 10. Regarding Eugia Defendants' Motion to Seal, the Eugia Defendants request that a page from Exhibit 2, four pages of Exhibit 3, two pages of Exhibit 10, two pages of Exhibit 11, (of ECF No 261), one page from Eugia's letter, (of ECF No. 270), one page of Exhibit Z, (of ECF No. 270), and nine lines of the transcript (of ECF No. 281) be redacted. The Court agrees that there is no less restrictive alternative to filing the information requested under seal because records cited to in this motion are entirely comprised of sensitive information. Mot. Seal, (ECF No. 347), Decl. George J. Barry, III at Index in Support of Motion to Seal. Cipla Defendants and Mankind Defendants request various redactions to Plaintiffs' Opening Markman Brief, (of ECF No. 310), the sealing of Exhibits 2, 10, and 12 (of ECF No. 310), redactions to Plaintiffs' Rebuttal Markman Brief, as well as Exhibit 20 in its entirety, (of ECF No. 333), redactions to Defendants' Rebuttal Markman Brief, (of ECF No. 335), and redactions to several pages of the Myerson Transcript, (of ECF No. 336). Mot. Seal (ECF No. 359), Decl. Loly G. Tor at ¶ 9; Decl. Jay P. Lesser at ¶ 7. The Court found that Cipla Defendants' and Mankind Defendants' approach of limited redaction and sealing applied to the confidential, non-public information to be the least restrictive means of protecting the confidential information contained in those documents. Similarly, Cipla Defendants request two pages to be

sealed of Exhibit 3 (of ECF No 332), one page of Defendants' response (of ECF No. 354), seven pages of Exhibit 1 (of ECF No. 356), and the entirety of Exhibit 3 (of ECF No. 357). The Court notes that prior sealing orders have included the portions of documents that Cipla Defendants are seeking to have sealed. The Court further notes that the approach taken here of limited redaction and sealing applied to the confidential, non-public information to be the least restrictive means of protecting the confidential information contained in those documents.

Further, the Court has reviewed the excerpts that all parties requested redactions be applied to and reviewed the documents that the parties have requested to seal and agree that the redactions and sealing of these select documents does not impede the public from understanding the legal arguments, factual circumstances, and the issues of dispute in the instant case.

Finally, Court also finds that there is "good cause" to protect such confidential information from disclosure. *See Faulman v. Sec. Mut. Fin. Life Ins.*, No. 04-5083, 2006 WL 1541059, at *1 (D.N.J. June 2, 2006) ("Generally, a court will protect materials containing 'trade secret[s] or other confidential research, development, or commercial information' to prevent harm to a litigant's competitive standing in the marketplace."); *see also Morgan v. Wal-Mart Stores, Inc.*, No. 14-4388, 2015 WL 3882748 at *2 (D.N.J. June 23, 2015) (granting motion to seal where "disclosure would result in the dissemination of confidential settlement negotiations and confidential settlement amounts" and where "the public has no legitimate interest" in gaining access to such confidential information in litigation between private parties). The fourth prerequisite is met, and thus the Court is satisfied that all motions satisfy the requirements of New Jersey Local Civil Rule 5.3. Therefore, each Motion to Seal discussed herein is granted in its entirety.

## V. CONCLUSION

For the reasons set forth above, the Court **GRANTS** the pending Motions to Seal, (ECF

Nos. 293, 347, 359, 381). An order consistent with this Opinion will be entered.

June 9, 2025

KAREN M. WILLIAMS, U.S.D.J.